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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JULIO BOZA

Appeal 2008-3430
Application 09/646,748
Technology Center 1600

Decided: September 24, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method for increasing plasma glutamine concentration. The Examiner has rejected the claims as anticipated and obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

"[G]lutamine is traditionally classified as [a] non-essential amino acid. The reason is that the body is generally able to synthesise sufficient

glutamine for its needs from glutamate and glutamic acid." (Spec. 1.) "[D]uring episodes of stress such as sepsis, injury, burns, inflammation, diarrhoea and surgery," however, "the body is not able to synthesise sufficient glutamine to meet its needs" (*id.*). "Therefore glutamine is now considered to be a conditionally essential amino acid for critically ill and other stressed patients" (*id.* at 2).

The Specification states that it "has been surprisingly discovered that the administration of nutritional compositions which contain whey protein, or a protein mixture which simulates the amino acid profile of whey protein, as a protein source increases plasma glutamine levels in humans or animals … despite the fact that whey protein contains relatively low amounts of glutamine" (*id.* at 3).

DISCUSSION

1. CLAIMS

Claims 1-16 are pending and on appeal. Claim 1 is representative and reads as follows:

> Claim 1: A method for increasing plasma glutamine concentration in a stressed mammal, the method comprising the step of
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> administering to the stressed mammal a nutritional composition including a protein source having at least 80% by weight of a component selected from the group consisting of
>
> whey protein, and
>
> a protein mixture which simulates the amino acid profile of whey protein consisting of approximately 80% to about 90% by weight of casein, approximately 0.5% to about 2% by weight of isoleucine, about 2% to about 8% by weight of leucine, about 1% to about 5% by weight of cysteine, and about 1% to about 5% by weight of lysine.

Claims 2 and 3, the other independent claims on appeal, are directed to a "method for increasing muscle glutamine concentrations in a mammal" and a "method for providing glutamine to a mammal suffering from injured, diseased or under-developed intestines," respectively. Claims 2 and 3 are otherwise identical to claim 1.

2. ANTICIPATION

Claims 1, 2 and 6 stand rejected under 35 U.S.C. § 102(b) as "anticipated by the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition (formerly known as Costello's)."[1] (Answer 3.)

The Examiner finds that the

> product of Optimum Nutrition as evidenced on the cited web site search discloses the superior blend of whey protein isolates, concentrates and hydrolysates, wherein the whey protein isolates as the primary protein source contains 100% whey protein. The cited product is useful as a dietary supplement for the intended purposes of increasing plasma glutamine concentration in [a] stressed mammal or for increasing muscle glutamine concentrations in a mammal.

(Ans. 3-4.) The Examiner also directed Appellant's attention to

> the front page of Costello's Health Distributor's 1997 product catalog (provided to the Office by Optimum Nutrition) along with a copy of the specific page of the catalog that lists **100% whey protein** product.

(Ans. 8-9.)

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[1] As we understand it, the Examiner originally relied on the sale of the Optimum Nutrition whey protein product as prior art (based on an undated web site) (Office Action mailed May 5, 2006) but subsequently provided Costello's 1997 Catalog as evidence that the product was on sale in 1997 (Office Action mailed May 8, 2006).

We agree with the Examiner that Costello's discloses the method of claim 2. The method defined by claim 2 has one step: administering to a mammal a nutritional composition that includes a protein source that is at least 80% by weight of, among other things, whey protein. Costello's discloses a nutritional supplement product (i.e., a composition intended to be administered to people) that is 100% whey protein. Given this disclosure, Costello's discloses the claimed method.

Appellant argues that "[i]t remains possible that *Costello's* nutritional product referred to by the Examiner does not disclose or suggest a *protein source having at least 80% by weight* of a whey protein" and that "Costello's nutritional product may also provide additional protein sources besides whey protein that amount to more than 20% of the total protein source" (App. Br. 11).

We are not persuaded by this argument. Given that Costello's discloses its nutritional product as being 100% whey protein, we find that the Examiner has set forth a reasonable basis on which to find that the reference teaches the administration of a nutritional composition comprising 100% whey protein. Further, claim 1 is drawn to a method of administering to a mammal "a nutritional composition including a protein source having at least 80% by weight" of, e.g., whey protein. Appellant contends that it is possible that another protein source that amounts to more than 20% of the total weight is present in Costello's product, i.e., that it contains less than 80% whey, but provides no evidence to support this possibility (App. Br. 11).

"As a patent term of art, 'includes' means 'comprising.' . . . Neither includes, nor comprising, forecloses additional elements that need not satisfy the stated claim limitations." *SanDisk Corp. v. Memorex Products, Inc*, 415 F.3d 1278, 1284 (Fed. Cir. 2005) (citations omitted). Thus, the claim only requires that some, not all, of the protein source be whey protein. In other words, Costello's product "includ[es] a protein source having at least 80% by weight of . . . whey protein" if it contains *any* amount of whey protein, even if mixed with other protein sources.

With regard to claim 1, Appellant also argues that "[c]laim 1 requires the method step comprising administering a nutritional compound to a stressed mammal to increase its plasma glutamine concentration" and that Costello's fails to disclose or suggest the element of administering the composition to a stressed mammal (Reply Br. 3).

The Examiner argues that the term "stressed mammal" is a non-limiting condition because all mammals experience at least some level of stress (Ans. 9).

We agree with Appellant that the Examiner has not adequately explained how the reference discloses administering the disclosed whey protein compositions specifically to a stressed mammal.

"It is axiomatic that, in proceedings before the PTO, claims in an application are to be given their broadest reasonable interpretation consistent with the specification and that claim language should be read in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Sneed*, 710 F.2d 1544, 1548 (Fed. Cir. 1983) (citation omitted).

Here, the Examiner has interpreted the claims as reading on any type of stress, without regard to the effect of the stress on plasma glutamine levels (Ans. 5). This reading of the claim is broader than would be considered reasonable in view of the Specification by a person of ordinary skill in the art. The Specification states that

> [d]uring periods of illness, the metabolic rate of glutamine increases and the body is not able to synthesise sufficient glutamine to meet its needs. This is particularly true during *episodes of stress such as sepsis, injury, burns, inflammation, diarrhoea and surgery*. During episodes of stress: there is a marked increase in glutamine consumption by the gastrointestinal tract, immune cells, inflammatory tissue and the kidney. This consumption may far outstrip the endogenous rate of synthesis of glutamine. . . . Similarly, pre-term babies have a lower rate of glutamine synthesis; often insufficient for needs. Further, it is found that athletes, after intense exercise, have reduced levels of glutamine in their plasma.

(Spec. 1, emphasis added.)

When the claims are read in light of the Specification, those of skill in the art would interpret "a stressed mammal," to mean an individual undergoing an episode of stress that causes reduced or insufficient plasma glutamine levels. We therefore conclude that the Examiner's claim interpretation is broader than would be considered reasonable by those of skill in the art, when read in light of the Specification.

Costello's discloses whey protein as a nutrition supplement but does not describe administration of the supplement to any particular group of people. The Examiner has not adequately explained how Costello's discloses the administration of the disclosed whey protein to a stressed mammal; i.e., one undergoing an episode of stress that causes reduced or

insufficient plasma glutamine levels. Therefore, the rejection of claim 1 as anticipated by Costello's is reversed. Claim 6 depends from claim 1; the rejection of claim 6 is therefore also reversed.

3. OBVIOUSNESS I

Claims 1-16 stand rejected under 35 U.S.C. § 103 as obvious in view of "the product 100% Whey Protein 5 lbs, which is available in the market by Optimum Nutrition (formerly known as Costello's)" and Ballèvre. [2] (Answer 4.) The claims have been argued in three groups: claims 1 and 6-10 (group 1), claims 2 and 11-13 (group 2), and claims 3-5 and 14-16 (group 3). The claims in each group stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii).

The Examiner relies on Costello's for the disclosure set forth above.

The Examiner finds that Ballèvre discloses "a nutritional composition comprising a protein source including whey protein and a protein mixture having the amino acid profile of whey protein which is administered to stressed patients to increase the plasma glutamine concentration, or administered as nutritional support for increasing muscle glutamine concentration in athletes after exercise, or administered to patients suffering from injured or diseased intestines" (Ans. 5).

The Examiner concludes that one of ordinary skill in the art would have been motivated to use the known whey protein product in the method of Ballèvre for the same purposes that protein supplements are disclosed in Ballèvre, i.e. for "increasing glutamine levels in plasma or muscle of a stressed patient, pre-term baby or athletes" (*id.* at 6).

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[2] Ballèvre et al., US 5,849,335, Dec. 15, 1998.

We conclude that the Examiner has set forth a prima facie case that claim 2 would have been obvious to the ordinary artisan. Costello's is discussed above. Ballèvre discloses a "nutritional composition for providing glutamine to a human or animal. . . [that] includes carob protein which is rich in glutamine" (Ballèvre, abstract). Ballèvre also discloses that the composition preferably also includes a source of Met or both Cys and Met; "[p]referably the source of Cys and Met is selected from whey or casein or both" (*id.* at col. 2, ll. 50-52). Whey can be included "for example in an amount of about 10% to about 30% by weight" (*id.* at col. 4, ll. 29-32).

Ballèvre discloses that enterally administering the composition increases plasma glutamine levels in a human or animal, and that the human or animal is preferably a stressed patient, preterm baby, or athlete (*id.* at col. 3, ll. 3-9). "Examples of stressed patients are patients who are critically ill, or who are suffering from sepsis, injury, burns, or inflammation, or patients recovering from surgery" (*id.* at col. 3, ll. 9-12). Ballèvre also discloses that disclosed compositions can be used to provide "glutamine to patients suffering from injured or diseased intestines" (*id.* at col. 3, ll. 19-25).

We agree with the Examiner that the teachings of Costello's and Ballèvre would have made obvious the invention of claim 2. Given the explicit suggestion in Ballèvre of adding whey protein to a carob protein composition used to treat stressed mammals or to raise plasma glutamine levels in mammals, one of skill in the art would have been motivated to add the Costello's whey protein product to the carob protein nutritional supplement of Ballèvre and administer the resulting composition to the mammals, people in particular.

Appellant argues that one of ordinary skill in the art would not be motivated to combine the cited references to arrive at the method of claim 2 because the "whole premise of *Ballevre* is that carob protein is rich in glutamine and that its nutritional composition for improving plasma glutamine should include carob protein" (App. Br. 12). Appellant argues that Ballèvre discloses that a "mixture of carob and whey proteins uses whey protein as the minor rather than the major component" (*id.*). Appellant further argues that "*Ballevre* discloses that carob protein comprises about 40% to about 100% by weight of the protein source," i.e. a minimum of 40% of the protein source as carob, and therefore Ballèvre teaches away from a combination with Costello's whey protein product.

We do not find this argument to be persuasive. As set forth above, claim 2 recites a product that "includes" (i.e., comprises) whey protein, and therefore does not foreclose additional elements. Thus, any amount of Costello's whey protein product could be included with the carob protein of Ballèvre and meet the limitation of the claim. Given that Ballèvre expressly discloses administering whey protein to a mammal (i.e. in conjunction with carob protein), one of skill in the art would have been motivated to administer whey protein to a mammal as recited in claim 2.

With regard to claim 1, Appellant further argues that the cited references fail "to disclose or suggest a method for increasing plasma glutamine concentration in a stressed mammal" as required by claim 1 (App. Br. 13).

We are not persuaded by this argument, because Ballèvre expressly suggests administering its composition to "a stressed patient," including

those who are critically ill, suffering from sepsis, injury, burns, or inflammation, or recovering from surgery (Ballèvre, col. 3, ll. 8-12). These are the same patient populations described as "stressed" in the instant Specification (Spec. 1). Therefore, Ballèvre would have suggested the administration of the claimed protein composition to a stressed mammal.

With regard to claim 3, Appellant further argues that Ballèvre also fails "to disclose or suggest a method for providing glutamine to a mammal suffering from injured, diseased or underdeveloped intestines" as required by claim 3 (App. Br. 13).

We are not persuaded by this argument, because Ballèvre expressly suggests glutamine supplementation for an individual with injured or diseased intestines (*see* Ballèvre, col. 3, ll. 19-25).

SUMMARY

The Examiner's rejection of claim 2 under 35 U.S.C. § 102(b) and claims 1-16 under 35 U.S.C. § 103 are supported by the preponderance of the evidence of record. We therefore affirm these rejections.

However, we agree with Appellant that the Examiner has not made out a prima facie case of anticipation of claims 1 and 6 based on the Costello's reference and we therefore reverse this rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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